

Application No. 10/662,223

### **REMARKS**

This is a Response to the Office Action dated September 14, 2006. Claims 1, 2, 4-7, and 25-32 are pending in this application. The Examiner has rejected Claims 1, 2, 4-7, and 25-32. Claims 4, 5, 7, 27, 31, and 32 have been amended.

#### ***Claim Rejections - 35 U.S.C. § 112, second paragraph***

Claims 4-7, 29, and 30 have been rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Examiner indicated that “the first and/or second element” in claims 4, 5, 7, 29, and 30 lack antecedent basis. Claims 4, 5, 7 and 27 have been amended to overcome the rejections. Applicants respectfully request removal of the rejections.

#### ***Claim Rejections - 35 U.S.C. § 102***

Claims 1, 4-6, and 27-32 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Kachigian (U.S. Patent No. 5,084,005). Applicants respectfully disagree.

The Examiner states that “Kachigian provides a swab useful for medical purposes and capable of supporting a stent comprising a member ... including a plurality of pores(34) disposed on the surface of the member.” Specifically, Kachigian discloses a swab for collecting biological samples that include, for example, microorganisms. (Abstract, Kachigian) Kachigian does not expressly disclose the size of the swab. Nor does Kachigian inherently provide any information on the size of the swab.

Claim 1 recites “an apparatus to support a stent during a process of coating the stent with a coating substance.” Claim 27 recites “a mounting assembly to support a stent during the application of a coating composition onto the stent.” Claims 31 and 32 recite “a support assembly to support a stent during a process of coating the stent with a composition.” Kachigian

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fails to teach or suggest the above limitations. Since Kachigian does not provide any information on the size of the swab, Kachigian does not teach that the swab is capable of supporting a stent.

Applicants recognize that apparatus claims must be structurally distinguishable from the prior art. MPEP Section 2114 states that “while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.” In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Although the above-mentioned limitations are functional, they also place structural limitations on the claimed apparatuses. A stent has a shape and size discernable from the prior art. Therefore, a member or element to support a stent must have a size and shape appropriate to support a stent. In order for a prior art reference to anticipate the above claims, it must provide express or inherent disclosure indicating that it has an appropriate size to support a stent. As indicated above, Kachigian does not.

In In Re Schreiber, the Court stated that “the absence of a disclosure in a prior art reference relating to function did not defeat the Board’s finding of anticipation of claimed apparatus because the limitations at issue were found to be inherent in the prior art reference.” The present situation is distinguishable from In Re Schreiber. Applicants’ claims are not anticipated because all of the structural limitations of the claims are not expressly or inherently disclosed by Kachigian. Thus, Kachigian does not teach or suggest all of the above-mentioned claim limitations.

Furthermore, claim 1 recites “the pores capable of receiving a coating substance during the coating process”; claim 27 recites “a layer to absorb a coating composition that comes into contact with the layer during the application process”; claim 31 recites “an absorbing layer disposed on the surface of the member for at least partially absorbing some of the composition that comes into contact with the absorbing layer”; and claim 32 recites “an absorbent material for

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at least partially absorbing some of the composition that comes into contact with the first element and/or the second element.” Kachigian does not teach or suggest the above-cited claim limitations. As indicated above, Kachigian teaches a porous swab to collect biological samples. There is no teaching that the porous swab can be used for or is capable of, for example, receiving a coating substance or absorbing a coating composition.

Additionally, claims 27, 31, and 32 recite “first element to make contact with one side of a stent, and a second element to make contact with another side of the stent.” Kachigian does not teach or suggest the above-mentioned limitation.

Therefore, claims 1, 27, 31, and 32 are patentable over Kachigian. Claims 4-6, 25, and 26 depend from claim 1 and are allowable for at least the same reason that claim 1 is allowable. Claims 28-30 depend from claim 27 and are allowable for at least the same reason that claim 27 is allowable.

Claims 27-29 and 30-32 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Sills (U.S. Patent No. 3,724,018). Applicants respectfully disagree.

Claims 27, 31, and 32 recite “first element to make contact with one side of a stent, and a second element to make contact with another side of the stent.” Sills does not teach or suggest the above-mentioned limitation. Claims 28-30 depend from claim 27 and are allowable for at least the same reason that claim 27 is allowable.

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***Claim Rejections - 35 U.S.C. § 103***

Claims 2 and 25 have been rejected under 35 U.S.C. § 103 as being unpatentable over Kachigian. Applicants respectfully disagree.

As indicated above, claim 1 is allowable over Kachigian. Claims 2 and 25 depend from claim 1 and are allowable for at least the same reason that claim 1 is allowable.

Claims 1, 2, 4-7, 25, and 26 have been rejected under 35 U.S.C. § 103 as being unpatentable over Jendersee et al. (U.S. Patent Number 5,836,965) in view of Helfrich (U.S. Patent No. 5,308,338), and Scanlon et al. (U.S. Patent No. 2,845,346). Applicants respectfully disagree.

Jendersee et al. disclose a stent support device including a balloon catheter for implanting a stent within a vascular system. (Abstract, Jendersee et al.) The Examiner indicates that Jendersee et al. teach a workholder comprising a tubular support member for supporting a stent having a cuffs or retaining members. The Examiner states that Jendersee et al. are silent concerning the retaining member(s) having a porosity to the extent of a closed pore system. Jendersee et al. generally fail to disclose that the retaining members can be porous or have a porous layer.

The Examiner indicates that “in light of the teachings of Jendersee et al that any implantable material can be used to make the retaining member(s), the teaching of Helfrich with respect to catheters having cuffs made from porous material (i.e., sintered metal), and the teaching of Scanlon et al, that sintered metal while porous, can be made to have a closed pore system, would have found it obvious to make the retaining member(s) of any appropriate porous and/or non-porous implantable material.” Applicants respectfully disagree.

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Jendersee et al. state that “retainers may be made from any implantable material, such as stainless steel or polymers.” The fact that “any implantable material” is followed by a generic reference to “polymer” and a type of metal does not indicate to a person of skill in the art that Jendersee et al. is referring to structural characteristics of a material such as shape or porosity. Thus, the use of the word “any” does not make obvious the use of any shape or structural characteristic in combination with the retaining members of Jendersee et al.

Furthermore, Jendersee et al. teach the importance of a smooth outer surface to facilitate positioning of the support device at an implant site. (col. 3, line 3, Jendersee et al.) A porous retaining member would be a rough surface and hinder passage of the delivery device through vessels. Therefore, the proposed modification is undesirable and there is no motivation for making it. Also, since the proposed modification would render the delivery device of Jendersee et al. unsatisfactory for its intended purpose, there is no suggestion or motivation to make the proposed modification. MPEP Section 2143.01 V

Additionally, Jendersee et al., Helfrich, or Scanlon et al. do not provide any suggestion or motivation for having porous retaining members in the stent delivery device of Jendersee et al. The Examiner has provided no evidence that the knowledge generally available to one of ordinary skill in the art provides such motivation or suggestion. As pointed out below, Rosenbluth et al., cited by the Examiner for establishing the state of stent coating art in which a catheter can serve the dual purpose of a workholder as well as a delivery device, provides no such motivation or suggestion.

The Examiner additionally states that “it would have been obvious to one of ordinary skill in the art to utilize any appropriate porous or nonporous implantable material from which to make the retaining member(s), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of

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obvious design choice.” Applicants respectfully disagree that it would be obvious to utilize a porous material for the retaining members of Jendersee et al. on this basis. As indicated above, the Examiner has provided no evidence or reason why one of ordinary skill in the art would consider a porous material suitable for use in the retaining members of Jendersee et al. In fact, applicants have shown that a porous material for the retaining members would be unsuitable and undesirable.

Since there is no motivation for the proposed combination of Jendersee et al. with Helfrich and Scanlon et al., the Examiner has not established a *prima facie* case of obviousness. Applicants respectfully request removal of the section 103 rejections of claims 1, 2, 4-7, 25, and 26.

In addition, the Examiner indicates that Scanlon et al. teach a closed pore construction at col. 1, lines 15-23:

This invention relates to sintered metal powder bodies which have interconnected pores and are ductile, coinable, and to the process of making such bodies to shape within narrow tolerances.

Among the objects of the invention is to provide a cemented metal particle body which is porous in some parts and of different porosity or of no porosity in other predetermined parts thereof, and to provide a process for making such a body.

Even if the cited references are combinable, a closed pore construction is not disclosed in the cited portion. Claim 1 recites “the pores have an open end and a closed end so as to provide a closed pore system on the surface of the member.” Neither Jendersee et al. nor Helfrich cure the deficiency of Scanlon et al. with respect to claim 1. Claims 2, 4-7, 25, and 26 depend from claim 1 are an allowable for at least the same reason that claim 1 is allowable.

Claims 27-32 have been rejected under 35 U.S.C. § 103 as being unpatentable over Jendersee et al. in view of Helfrich. Applicants respectfully disagree.

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The Examiner indicates that Jendersee et al. teach a workholder comprising a tubular support member for supporting a stent having cuff(s) or retaining member(s), but are silent concerning the cuff(s) or retaining member(s) having a porous layer. The Examiner further states that “it would have been obvious to one of ordinary skill in the art to make the cuff(s) or retaining member(s) of a porous layer material as taught by Helfrich in the device of Jendersee et al. in order to enable the absorption or retention of fluid when the stent is pretreated or enable tissue grown when the device is implanted. Applicants respectfully disagree with the Examiner’s motivation for the proposed combination.

Jendersee et al. disclose a support device including a balloon catheter for implanting a stent within a vascular system. (Abstract, Jendersee et al.) Neither Jendersee et al. nor Helfrich mention anything about pretreating a stent prior to implantation. The Examiner cites Rosenbluth et al. for establishing the state of stent coating art in which a catheter can serve the dual purpose of a workholder as well as a delivery device. Rosenbluth et al. disclose coating a catheter and stent mounted on the catheter with a lubricant prior to delivery of the stent. (col. 13, line 37, Rosenbluth et al.) However, there is no reason to provide a porous member on a support member to absorb the lubricant. On the contrary, absorption of the lubricant would not be desirable since one would want the lubricant to stay on the surface of the stent and support so that lubricant can facilitate delivery of the stent. Furthermore, there is no suggestion that excess lubricant presents a problem and needs to be removed, for example, through absorption by a porous member. Thus, there would be no reason for one of skill in the art to modify the device of Jendersee et al. to have porous retaining members.

Furthermore, the Examiner’s suggestion that there is a need for the absorption or retention of fluid applied to a stent appears to be taken from Applicants’ own disclosure. Thus,

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the Examiner's conclusion of obviousness is based on improper hindsight reasoning. MPEP Section 2145 X.

With regard to the Examiner's other motivation, promoting tissue growth between the support device of Jendersee et al. and a vascular wall not desirable. The device with porous cuffs taught by Helfrich is designed to be secured or anchored at an implant site, the cuffs being of a woven material that promotes tissue ingrowth (Abstract, Helfrich). However, the support device of Jendersee et al. is removed upon expansion of the stent at an implant site (col. 8, lines 19-22, Jendersee et al.). The tissue ingrowth during the delivery process would likely be nonexistent or inconsequential. There is no motivation either in Helfich or Jendersee et al. for making the proposed modification of Jendersee et al. Even if there was some ingrowth, it would be undesirable since the ingrowth would hinder removal of the support device, making it unsuitable for its intended use. This unsuitability negates the motivation for the Examiner's proposed modification. MPEP Section 2143.01 V. Additionally, as indicated above, a porous retaining member would be a rough surface and hinder passage of the delivery device through vessels.

Since there is no motivation for the proposed combination, the Examiner has not established a *prima facie* case of obviousness. Applicants respectfully request removal of the section 103 rejections of claims 27-32.

Claims 1, 2, 4-6, and 25-32 have been rejected under 35 U.S.C. § 103 as being unpatentable over Frisch (U.S. Patent No. 4,906,423). Applicants respectfully disagree.

The Examiner states that Frisch teaches a member with a plurality of pores, but does not explicitly teach the device being exclusively of a closed cell construction. The Examiner further states that "Frisch recognizes that some cells can be of a closed cell construction, it would have



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been within the purview of one skilled in the art to determine, via routine experimentation, the appropriate foam material to employ to arrive at a closed cell pore device.” Applicants respectfully disagree. Frisch specifically teaches against the foamed material being exclusively of a closed cell construction:

The foams may have various ratios of open cell to closed cells: however, the foam’s surface needs (*emphasis added*) some open cells in order for the polymeric composition to penetrate into the foam to form a porous-surfaced body. (Col. 3, lines 61-65, Frisch)

Since the foam’s surface in Frisch needs some open cells, there is no motivation for the Examiner’s proposed modification. Additionally, since the foam’s surface in Frisch needs some open cells for the polymeric composition to penetrate into the foam, the modification of the device of Frisch making it exclusively a closed cell pore device would render it unsatisfactory for its intended purpose, negating any motivation for the proposed modification. MPEP Section 2143.01 V. Thus, one of skill in the art would not have a reason to determine, via routine experimentation, an appropriate foam material to employ to arrive at a closed cell pore device.

The Examiner further states that “the term ‘comprising’ is deemed open ended language which would not exclude the teachings of Frisch to the use of a few open cells in combination with a closed pore system.” Applicants respectfully disagree.

Claim 1 recites “comprising a member including a plurality of pores disposed on a surface of the member.” The open-ended term “comprising” refers to “member” and not the characterization of the pore system on the member. “Comprising a member” means that the claimed device can include at least one additional member, in addition to the claimed member. The member of Frisch with “a few open cells” does not teach the limitation of the claimed member, “the pores have an open end and a closed end so as to provide a closed pore system on the surface of the member.” Thus, Frisch discloses a porous member that applicants do not claim

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and specifically teaches against the member that applicants do claim. Claims 2, 4-6, 25, and 26 depend from claim 1 and are allowable for at least the same reason that claim 1 is allowable.

Claims 27, 31, and 32 teach a "first element to make contact with one side of a stent, and a second element to make contact with another side of the stent. Frisch does not teach or suggest the above-mentioned claim limitation. Thus, claims 27, 31, and 32 are allowable. Claims 28-30 depend from claim 27 and are allowable for at least the same reason that claim 27 is allowable.

### **CONCLUSION**

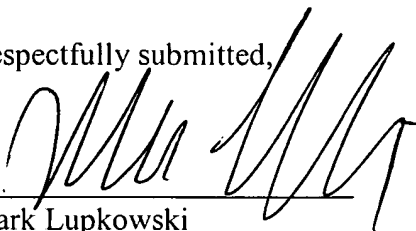
Claims 1, 2, 4-7, and 25-32 are pending in this application. Examination and allowance of the claims are respectfully requested.

If the Examiner has any questions or needs any additional information, the Examiner is invited to telephone the undersigned attorney at (415) 954-0297.

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Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza, Suite 300  
San Francisco, CA 94111  
Telephone (415) 954-0297  
Facsimile (415) 393-9887

Respectfully submitted,



Mark Lupkowski  
Attorney for Applicants  
Reg. No. 49,010